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(54) Title: IMPROVEMENTS IN PHALLOPLASTY

(57) Abstract: A method of penis lengthening including dividing the suspensory ligament down to the inferior public arch; dividing the fundiform ligaments; or dividing the first and second corpus cavernosum circumferentially. A method of widening a penis where a dermal fat graft is sutured to the exposed Bucks fascia. Post operative drug and exercise to maintain the outcome of penis lengthening or widening.

WO 03/082120 A1

IMPROVEMENTS IN PHALLOPLASTY

This invention relates to enhancement phalloplasty, which is a surgical procedure to modify the human penis, normally by increasing the length of or widening the penis.

5

BACKGROUND

There are several reasons for persons requiring operations of this type. The first is for persons who are born with small penises. These persons can often believe
10 that they are the subject of derision and ridicule and the lack of size of the appendage can be emotionally very difficult for them.

A second is where persons, either for personal pleasure or for professional reasons, such as strip-tease dancers,
15 actors and the like, wish to be seen to have a large penis.

There have been previously proposed methods of enhancement phalloplasty but these have not been fully successful.

The major object of the invention is to provide methods
20 of enhancement phalloplasty which provide satisfactory results and which are safe procedures and which result in lengthening the penis in both the flaccid and erect states.

The applicant has disclosed basic surgical procedures in earlier filed patent applications including Australian Patent

- 2 -

Applications 28601/97, 53864/98 and 79900/98. However these applications are for a base surgical procedure. It is an object of the present invention to combine these surgical procedures and others with post-operative treatment methods
5 thereby to maintain the outcome of the basic surgical procedure.

BRIEF DESCRIPTION OF INVENTION

Accordingly, in one broad form of the invention there is
10 provided a method for penile enlargement further including the step of application of a post-operative treatment regime.

Accordingly, in another broad form of the invention there is provided a method for penile enlargement further including the step of application of a post-operative
15 treatment regime thereby to maintain outcome of enlargement.

Accordingly, in yet another broad form of the invention there is provided a method of widening a penis wherein a dermal fat graft comprising a block of fat and attached dermis is excised from the patient, the penis is degloved,
20 the dermal fat graft is sutured to the exposed Bucks fascia and then reducing the penile skin; said method further including the step of following a post-operative treatment regime.

- 3 -

Preferably the dermal fat grafts are harvested from either the buttocks, lower back or lower abdomen.

Accordingly, in yet another broad form of the invention there is provided a method of lengthening the penis of a male
5 which includes the steps of placing the suspensory ligament under tension in the inferior direction; dividing the suspensory ligament against the body of the symphysis pubis down to the inferior pubic arch and along the inferior surface of both the right and left conjoined inferior pubic
10 rami; effecting suturing to retain the penis released from the suspensory ligament in an inferior position by coapting the proximal medial attachments of the right and left gracilis muscle together ventral the released penis, dividing the fundiform ligaments, drawing the skin of the junction
15 site of the scrotum and the perineum mediosuperiorally so as to attach it to the symphysis pubis thereby pushing the skin adjacent thereto along the newly exposed shaft of the penis and suturing this to retain this position; said method further including the step of following a post operative
20 treatment regime.

Preferably followed by the insertion of additional sutures through the anterior surface of the symphysis pubis; said sutures also placed through the margins of the pubic

- 4 -

skin wound and tied in such a manner as to pull suprapubic skin down infrapubically.

Preferably the number of said additional sutures inserted is 1 or more.

5 Preferably the number of said additional sutures is determined by the width of the symphysis pubis.

Preferably including the step of dividing the fundiform ligament prior to said step of drawing the skin of the junction site of the scrotum.

10 Accordingly, in yet another broad form of the invention there is provided a method of widening a penis wherein a block of fat and attached dermis (dermal fat graft) is excised from the patient, the penis is degloved, the dermal fat graft is sutured to the exposed Bucks fascia and then
15 reducing the penile skin.

Preferably the dermal fat grafts are harvested from either the buttocks, lower back or lower abdomen.

Preferably the dermal fat graft is sutured to the exposed Bucks fascia prior to the tying of the sutures which
20 maintain the lengthening of the penis.

Accordingly, in yet another broad form of the invention there is provided a method of enhancement phalloplasty of a human penis in patients who are about to have or already have in place an artificial erection device; said penis having a

- 5 -

structure including a first corpus cavernosum, a second corpus cavernosum, a corpus spongiosum, a Buck's fascia and a dorsal neurovascular bundle; said method including the steps of degloving the penis to expose the Buck's fascia; freeing the dorsal neurovascular bundle and separating the corpus spongiosum from the inferior surface of both said first and said second corpus cavernosum; dividing said first and second corpus cavernosum circumferentially; said method further including the step of following a post-operative treatment regime.

Preferably said step of separating the corpus spongiosum from the inferior surface of both said first and said second corpus cavernosum comprises a dissection so as to enable the first and second corpus cavernosum to be elongated without dividing the corpus spongiosum.

Preferably said artificial erection device comprises a corporal cylinder which is longer than the corporal cylinder presently in place, either where the patient already has an artificial erection device in place or longer than the corporal cylinder which was measured when the corporotomy and dilatation of the corpus was performed earlier in the procedure.

Preferably the increase in length of the corporal cylinder is of the order of one or more cm.

- 6 -

Preferably a gap formed in the first or second corpus cavernosum is filled by suturing in place an inverted dermal graft from which the epidermis has been removed.

Preferably the dermo epidermal surface is the inner most
5 surface applied to the corporal cavity.

Preferably widening of the penis is also required and wherein widening is effected by using a dermal fat graft.

Preferably the fat graft is sutured to the exposed Bucks fascia and when the graft reaches a defect in the Buck's
10 fascia corresponding to the division of the first or second corpus cavernosum the edges of the graft are sutured to the Buck's fascia circumferentially and to a distal portion of the first or second corpus cavernosum without dividing the graft as a separate phenomenon.

15 Preferably if the patient has a very thickened wall of the first or second corpus cavernosum, a first dermal fat graft is placed into the defect in the Buck's fascia and then a second dermal fat graft is placed into the defect.

Preferably if the patient has a very thickened wall of
20 the corpus cavernosum, the gap in the wall of the corpus cavernosum is filled by using a gortex graft, a saphenous or other vein patch, temporalis or other fascia such as the fascia lata or dextron mesh or silastic sheeting or other appropriate material and then said second dermal fat graft is

- 7 -

applied.

Preferably further including an additional step wherein the degloved penis is reduced and the proximal wounds are trimmed and closed in layers.

5 Accordingly, in yet another broad form of the invention there is provided a method of enhancement phalloplasty substantially as hereinbefore described with reference to the examples of the particular operations given in the specification.

10 Preferably penile enlargement comprises one or more of lengthening or widening.

Preferably further including the step of treatment for buried penis condition.

Preferably said post-operative treatment regime
15 comprises application of a drug treatment regime.

Preferably said post-operative treatment regime comprises application of an exercise regime.

Accordingly, in yet a further broad form of the invention there is provided an exercise regime for
20 application following application of the above described method.

Accordingly, in yet a further broad form of the invention there is provided a drug treatment regime for application following application of the above described

method.

Accordingly, in yet a further broad form of the invention there is provided a method of lengthening and widening a penis, the lengthening using the method as
5 described above wherein a block of fat and attached dermis (dermal fat graft) is excised from the patient, the penis is degloved, the dermal fat graft is sutured to the exposed Bucks fascia prior to the tying of the sutures which maintain the lengthening of the penis.

10

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

In order that preferred embodiments of the invention may be more readily understood, I will describe certain procedures in greater detail below.

15

The first of these has to do with penile enlargement. This involves suprapubic (or other type) incision and exposure of the suspensory and fundiform ligaments of the penis and their division under direct vision from the suprapubic area and the inferior bodies of the pubic arch
20 (i.e. all of the antero-inferior surface of the pubic symphysis. The penis is depressed posteriorly by approximating the medial edges of the upper ends of the right and left Gracilis muscle in front of the penis. The suprapubic skin is rearranged (by Zplasty, excision or a

- 9 -

combination of both) and sutured together and to the superior and anterior surfaces of the body of the pubis right and left.

To aid in the full understanding of the invention, I
5 will more fully describe the procedures of preferred embodiments:

PENILE LENGTHENING

10 With the patient under general aesthesia and in the supine position the lower abdomen, perineum and thighs are prepared and draped. In the classic procedure, a transverse suprapubic incision is made measuring approximately 3cm in length. Various other incision can be used such as W plastys, Z plastys, vertical and peno-scrotal incisions and the like.

15 The incision site and the adjacent mons tissues are infiltrated with local anaesthetic and adrenalin. The tissues overlying the mons veneris are separated laterally and the fundiform and suspensory ligaments of the penis are visualized.

20 Dissection is carried down by a blunt technique on either side of the suspensory ligament which is then divided under direct vision using diathermy. The dissection is carried out against the body of the symphysis pubis down to the inferior pubic arch level and along the conjoined rami of

- 10 -

ischium and pubis for a short distance. During the maneuver the assistant pulls the penis in an inferior direction placing the ligament under tension and it can be seen under direct vision and the neurovascular bundles can also be
5 directly visualized and preserved.

At this point, an O Maxon (or other suture material) deep stay suture is inserted into the deep surface of the pubic symphysis and then carried around the right Gracilis fascia and muscle across to the left Gracilis fascia and
10 muscle and the suture left loose. A second O Maxon (or other suture material) is then inserted distal to the first suture so as to further coapt the right and left Gracilis muscles in front of the penis. Two more deep stay sutures of O Maxon (or other suture material) are then inserted into the pubic
15 bone inferior surface laterally and left untied. A fifth, sixth and seventh O Maxon (or other suture material) suture are placed into the very superior edge and anterior surface of the exposed symphysis pubis and left untied.

The first deep stay suture of O Maxon is then tied
20 commencing with the one involving both Gracili which can be observed to approximate in front of the inferiorly depressed shaft of the penis followed by tying the second O Maxon Gracilis suture. The tissues on each side of the mons veneris at this point are then dissected and the fundiform

- 11 -

ligaments which are now clearly outlined as a result of this dissection are also divided under direct vision down to but not including the tissues overlying the spermatic cords on either side. The junction of the perineal and scrotal skin
5 on either side is then identified approximately 3cm lateral to the midline and one each of the remaining third and fourth O Maxon (or other suture material) sutures is/are inserted into the deep layers of the dermis of the scrotum on each side and the sutures tied. This draws the skin of the
10 junction side of the scrotum and perineum mediosuperiorally pushing the skin adjacent to it along the newly exposed shaft of the penis. The fifth, sixth and seventh O Maxon suture are inserted into the deep layers of the suprapubic incision in the centre and on either side and are tied so as to gently
15 curve the skin of the mons veneris down over the top of the symphysis pubis further aiding the movement of the abdominal skin onto the new penile shaft.

After trimming the wound is closed in layers and dressings are applied.

20

PENILE WIDENING BY DERMAL FAT GRAFT

With the patient under satisfactory general aesthesia and in the prone position, the buttock, anal area and thighs are prepared and draped. The areas of incision at the

- 12 -

5 buttock/thigh fold on both legs, which were previously marked, are infiltrated with a mixture of local anaesthetic and adrenalin and then the outer layers of the epidermis are dissected off over an area measuring of the order of 5 x 10cm or more cms. The actual size will be determined by the initial size of the penis measured preoperatively. Once the epidermis has been dissected free it is discarded. The exposed dermis, together with its layer of subtenant fat measuring approximately 2cm deep is excised en bloc using a mixture of cautery and sharp dissection.

10 The graft is then wrapped in a pack soaked in cold Ringer's solution and kept at room temperature (0 to 10 degrees Centigrade). The wound is closed in layers. Dressings are applied.

15 The patient is then turned from the prone to the supine position while still anaesthetized and the lower abdomen, perineum and thighs prepared and draped.

The area of the incision is then infiltrated with a mixture of local anaesthetic and adrenalin.

20 If widening is done in conjunction with lengthening, the incision is usually transverse though it may be any combination of the incisions described under lengthening, above including the peno-scrotal incision. If widening is

- 13 -

done alone then a transverse suprapubic incision is usually used although any of the above incisions may be used.

If the patient is already circumcised, infiltration of the old circumcision scar in its anterior half may also be carried out. If the patient is not circumcised it is necessary to proceed to circumcision usually, as this is a requirement for dermal fat grafting usually (though not always), then the entire circumference of the penis at the proposed circumcision site is infiltrated with local anaesthetic and adrenalin.

If the peno-scrotal approach is being used with degloving of the penis, then a completely circumferential infiltrate with local anaesthetic is used whether the patient is circumcised or not.

Once the incision, be it peno-scrotal, or more commonly transverse suprapubic, has been carried down to the deeper layers by blunt dissection, the skin and superficial fascia of the penis is separated from the shaft of the underlying penis in its entire length and circumference.

At this point, the anterior half of the old circumcision scar may be reopened (in the case of the suprapubic transverse incision) or the entire old circumcision scar or a new circumcision site is opened in the case of the uncircumcised who require circumcision, and in the case of

- 14 -

the peno-scrotal approach in the former. The penis is then degloved. The dermal fat graft is then sutured to the exposed Bucks fascia commencing on the coronal groove distally and going as far proximally as is possible with the wound exposure. This should be at least well down into the infra pubic region of the symphyseal or mid-portion of the penile shaft. The graft is attached all around the shaft of the penis leaving only the corpus spongiosum exposed.

The penile skin is then reduced, the circumcision wound (if applicable) is then closed as is the peno-scrotal incision if it has been used after the dartos fascia has been closed.

If the suprapubic incision has been used it is closed in layers. Telfa is applied to the wounds and the penis is encased in a crepe bandage as a moderately compressed dressing.

COMBINED PENILE LENGTHENING AND WIDENING

With the patient in the prone position, the dermal fat grafts are harvested as described above. The patient is then turned to the supine position and the operation proceeds as described under penile lengthening to the point where all of the deep stay sutures are in place but not tied. At this time, the distal circumferential incision (circumcision site

- 15 -

incision if required) is performed, the penile skin is developed and the penis degloved. The dermal fat graft is then sutured into place as described above.

Once the penile skin has been reduced, the deep stay
5 sutures are then tied as described above in regard to penile lengthening and attached to their other structures. All wounds are then closed as described above.

POST-OPERATIVE TREATMENT REGIMES

10 The abovementioned procedures advantageously are applied in combination with one or more of the following post-operative treatment regimes, namely either one or both of the stretching exercise or the drug treatment regime.

15 POST-OPERATIVE PENILE SCAR STRETCHING EXERCISE

THE EXERCISE: The Patient stands with the right leg flexed to 90 degrees at the right (left) hip joint.

The Right (left) foot is resting on a chair or stool such that the right (left) knee is also at a right angle.

20 The right (left) hand is passed around the right (left) thigh from outside, under, & inside the right (left) thigh & using the index finger & thumb of the right (left) hand the Glans (head) of the Penis is grasped (only the Glans & NO part of the shaft skin) & pulled down & back so that the penis is

- 16 -

pulled down & back between the Testicles & back towards the Anus. The patient pulls as hard as he can tolerate & should feel a strong pulling sensation at the base of the penis.

TIMING: The exercise consists of ten (10) pulls (five
5 (5) using the right hand & leg , & five (5) using the left hand & leg. Each pull is for ten(10) seconds & the patient may time this using a clock or simply count 1 & ,2 & , 3 & ,4 & , 5 & , 6 & , 7 & , 8 & , 9 & , 10 & . The patient rests for one
10 (1) second reapplies his grip to the Glans & pulls again for another ten (10) seconds.

This is repeated for ten (10) pulls each for ten (10) seconds. Ten (10) such pulls, each for ten (10) seconds constitute one block of exercises. The patient is required to perform three blocks per day viz. one block on first getting
15 out of bed in the morning, one block when he gets home from work, & one block just prior to going to bed at night (a total of thirty (30) pulls per day in three blocks of ten pulls).

It is to be understood that one can use a variety of
20 combinations of timing and number of pulls. Each pull will always be for 10 seconds, or multiples of 10 seconds. The number of pulls may vary and may be in excess of 100. The preferred number of exercise blocks per day is normally 3, but this may be varied to suit the specific situation.

- 17 -

Preferred ranges: 10 seconds minimum with an absolute minimum of 5 seconds. Multiples of this period may run up to a maximum of 100 seconds.

A possible formula to use to determine the overall regime is: pulls x seconds x repetition regime (minimum 300, maximum 1200) which can be termed the penile scar ergonomic factor.

The above regime can be used following one or more of the following operative procedures:

10

POST OPERATIVE DRUG TREATMENT REGIME

A treatment regime which can be used to advantage in respect of any of the above described procedures.

Initially, post-operatively a drug treatment regime can include the following:

Cephalexin (Monohydrate) - 500mg orally three times a day for 14 days - controls gram positive organisms, particularly staff and the like;

Combination: Amoxycillin (Trihydrate) and Clavulamic Acid e.g. Augmentin Duoforte - one tablet twice a day orally for two weeks - deals with organisms not commonly found at the operation site so as to lower wound infection rate;

Al Prazolam - 0.5-1mg orally three times a day for two weeks to suppress erections;

- 18 -

Ketoconazole - 400mg post-operatively three times per day for two weeks - again to suppress erections;

Mersyndol Forte - 2 capsules at night for two weeks - again to suppress erection;

5 Prednisone - A regime of 10mg three times a day for five days followed by 10mg twice a day for three days followed by 5mg twice a day for two days followed by 5mg once a day for two days - for the purpose of minimising the amount of local tissue swelling.

10

TREATMENT OF BURIED PENIS

Now follows a description of the treatment of buried penis by a combination of reconstruction of the pubic area, with elevation of the parapenile and supra-penile tissues so
15 as to reveal the buried penis in conjunction with enhancement phalloplasty as described above.

The purpose of the procedure is to enlarge the penis by recognising that in some individuals in addition to the penis having a small length and diameter it may also be partly
20 buried in a proptosed supra-pubic mound.

When done in conjunction with a phalloplasty the graft donation site can be the supra-pubic area and the size of the incision is largely determined by the size of the graft

- 19 -

required to widen the penis by the technique of dermal fat grafting described above.

The incision (previously determined by the size of required grafts for widening) is an elliptical incision
5 widest in the midline and narrowest laterally both right and left and is made in the supra-pubic area and a block of skin and fat is removed down to the level of the external oblique. Dermal fat grafts are harvested from this excised skin/fat block which is divided in the midline vertically so as to
10 produce two grafts of equal size.

The grafts are harvested by making an initial incision in the skin and then by sharp dissection removing the epidermis. The resultant dermis and fat block is then excised enmasse divided in two and used as the two grafts.
15 The infra-pubic space is then developed in the same way as for penile lengthening.

When the deep stay sutures are in place two x 0 maxon sutures are used to approximate the gracilis in front of the displaced penis and one x 1 nylon deep stay suture is placed
20 in the front of the pubic symphysis and this will be used to bring the skin just proximal to the base of the penis down onto the front of the pubic symphysis.

- 20 -

At this stage the penis is de-gloved and the grafts sutured in place as for penile widening with dermal fat grafts.

After the grafts are in place and the penile skin has
5 been reduced the nylon stay suture is inserted as described and this midline skin proximal to the penis is fixed to the front of the pubic symphysis on its infra-pubic surface. The tissues on either side are then elevated and sutured to the external oblique upon-neurosis using 1 nylon interrupted
10 sutures.

Closure of the superior border of the defect created by extracting the grafts is achieved with a combination of undercutting of the fat against the external oblique upon-neurosis combined with a vertical plication of the external
15 oblique sufficient to allow approximation of the two edges of skin without tension.

Deep stay suture on the front of the symphysis pubis and the attachment of the inferior margin of the wound to the external oblique and the longitudinal plication of the
20 external oblique in order to bring the upper margin down so that closure is achieved without tension and the whole effect being to raise the infra-pubic and para-penile tissues back up onto the upper surface of the pubic bone and lower abdominal wall.

- 21 -

ENHANCEMENT WITH ARTIFICIAL ERECTION DEVICE:

In its broadest aspect, the invention includes a method of enhancement phalloplasty of a human penis including the steps of degloving the penis to expose Buck's fascia and
5 dividing the corpora cavernosa circumferentially after freeing the dorsal neurovascular bundles and separating the corpus spongiosum from the inferior surface of both corpora cavernosa.

The method can provide an increase in length of the
10 penis of the order of one centimeter and thus the corporal cylinder to be used is longer by this amount than that presently in place or that which was measured when the corporotomy and dilatation of the corpus was performed earlier in the procedure.

15 The particular application to which the procedure specifically relates is to penile lengthening in patients who are about to have or already have in place an artificial erection device either of the inflatable or solid rod type as treatment for their impotence and who require additional
20 penile lengthening and/or widening.

In association with the method of the invention, I can also apply the lengthening and widening techniques described earlier in this specification in conjunction with the treatment regimes earlier described.

- 22 -

The dissection involves separating the corpus spongiosum from the inferior surface of both corpora cavernosa. Additional length of 1cm or more in the length of the corpus cavernosum can be obtained by this technique and so it will
5 be necessary to either put a 1cm longer corporal cylinder than has already been in place or a 1cm longer cylinder than has been measured at the earlier part of the procedure when the corporotomy and dilatation of the corpus was performed. The gap in the corpus cavernosum is filled by suturing in
10 place an inverted dermal graft from which the epidermis has been removed so that the dermo epidermal surface is the inner most surface applied to the corporal cavity.

Suturing is achieved using a continuous non-absorbable suture of the gortex type and suturing is performed over the
15 deflated corporal cylinder (in the case of inflatable cylinders) or over the rigid non-inflatable intra corporal rod if this has been used.

If widening using a dermal fat graft is also desired then the dermal fat graft is sutured in place generally as
20 described in my earlier patent application but when the graft reaches the defect in Buck's fascia corresponding to the division of the corpus cavernosum the edges of the graft are sutured to this circumferentially and to the distal portion of the corpus cavernosum without dividing the graft as a

- 23 -

separate phenomenon. However in those patients in whom there is a very thickened wall of the corpus cavernosum a better result can be achieved by putting a separate dermal graft into the defect and then applying another dermal fat graft more superficially to that as described earlier in this specification. The same result can be achieved by filling the gap in the wall of the corpus cavernosum by using a gortex graft, a saphenous or other vein patch, temporalis or other fascia such as the fascia lata. Even substances such as dextron mesh or silastic sheeting are also theoretically possible.

In order that the invention may be more readily understood, I will describe one particular operation in which the use of the invention is demonstrated.

This operation may be combined with penile lengthening or lengthening and widening as described earlier in this specification or it may be performed alone. It should also be noted that the artificial erection device can be put in by the classic infrapubic or penoscrotal technique. If the latter is used it will be necessary to perform the penile lengthening by dividing the suspensory ligament having approached it by a vertical (or other) suprapubic incision.

Once the suspensory ligament of the penis and the deep stay sutures have been inserted as described above then the artificial erection device is inserted as per the classical

- 24 -

description of the operation via the infrapubic or penoscrotal route as described widely in the general urological and surgical literature. Since additional length in the corpora cavernosa will be achieved by the technique of corporal division which is described hereinafter, the length of the corporal cylinder chosen for the artificial erection device should be 1cm or longer than that already measured for the insertion of that device. If the device has previously been inserted at a previous operation then it will be necessary to reopen the corporal cylinder and either attach a further 1cm rear tip extender or put in the same number of rear tip extenders as put in at the previous operation and add a 1cm longer cylinder which must be new or some combination of those two possible techniques.

Once the artificial erection device is in place the penis is degloved, the artificial erection device fully inflated and the dorsal neurovascular bundle of the penis on either side of the midline dissected free from an area approximately 2cm proximal to the coronal groove. This dissection is carried proximally and distally for 1cm so that the entire area of mobilisation is at least 2cm long. At the midpoint of this dissection the underlying corpus cavernosum on either side is incised and that incision is carried around medially in the midline or laterally around to the junction

- 25 -

with the corpus spongiosum. This latter structure is then carefully dissected away from the corpus cavernosum so that it is separated intact over an area of approximately 1cm. The division of the corpus cavernosum is then completed. The
5 artificial erection device is then fully inflated and maximum separation of the corpus cavernosa is achieved. At this stage a dermal graft taken from the original site of dermal fat graft donor area is stripped of its fat and sutured in the circumferential manner to the free margins of the corpus
10 cavnosum using a continuous non-absorbable suture such as 20 Gortex. When the wall of the corpus cavernosum is quite thin and when widening of the shaft of the penis is also being simultaneously achieved using a dermal fat graft a separate dermal graft to fill this defect is not necessary and the
15 deep layers of the dermal fat graft can be sutured to the free edges of the corpus cavnosum instead. During the suturing process it is both important more convenient for the artificial erection device to be deflated thereby minimising the risk of perforation of that device with the needle during
20 the suturing process.

At this stage the degloved penis is then reduced, the distal penile skin incision is closed with a running absorbable suture, the deep stay sutures in the infrapubic region are tied, the proximal wounds are trimmed and closed

- 26 -

in layers and dressings are applied.

If the artificial erection device has been in place for some time it is then inflated and left inflated for 24 hours. Dressings are then applied. If the artificial erection device
5 has been put in at the time of surgery as a new device then it is left deflated and a tight circumferential penile dressing applied.

FENESTRATION TECHNIQUE

10 In a variation of the above described technique for enhancement in the context of the existence of an artificial erection device the penis can be dismembered utilising the following alternative technique to circumferential division and graft in one place:

15 The fenestration technique comprises separation of the three corpora along the entire length of the penile shaft external to the perineum.

The corpora cavernosa are then incised from 12 o'clock to 6 o'clock on the right hand side of each corpus; a
20 distance of approximately 1cm (or more or less) between each incision.

Then the left hand side of each corpus is incised from 12 o'clock to 6 o'clock midway between two adjacent right

- 27 -

hand incisions and this series of alternate incisions is carried the entire length of the penile shaft.

Whilst I have described herein specific embodiments of the concepts of the present invention it is to be understood
5 that variations can be made in this within the ambit of the invention.

For example a modification on the above fenestration technique can comprise lateral fenestration only of the corpora cavernosa with or without separation of the three
10 corpora.

- 28 -

Claims:

1. A method of widening a penis wherein a dermal fat graft comprising a block of fat and attached dermis is excised from the patient, the penis is degloved, the dermal fat graft is sutured to the exposed Bucks fascia and then
5 reducing the penile skin; said method further including the step of following a post-operative treatment regime.
2. The method as claimed in Claim 1 wherein the dermal fat grafts are harvested from either the buttocks, lower
10 back or lower abdomen.
3. A method of widening a penis substantially as herein described.
4. A method of lengthening the penis of a male which includes the steps of placing the suspensory ligament under tension in the inferior direction; dividing the
15 suspensory ligament against the body of the symphysis pubis down to the inferior pubic arch and along the inferior surface of both the right and left conjoined inferior pubic rami; effecting suturing to retain the penis released from the suspensory ligament in an
20 inferior position by coapting the proximal medial attachments of the right and left gracilis muscle together ventral the released penis, dividing the fundiform ligaments, drawing the skin of the junction

- 29 -

site of the scrotum and the perineum mediosuperiorally so as to attach it to the symphysis pubis thereby pushing the skin adjacent thereto along the newly exposed shaft of the penis and suturing this to retain this position; said method further including the step of following a post operative treatment regime.

- 5 5. The method of Claim 4 followed by the insertion of additional sutures through the anterior surface of the symphysis pubis; said sutures also placed through the margins of the pubic skin wound and tied in such a manner as to pull suprapubic skin down infrapubically.
- 10 6. The method of Claim 5 wherein the number of said additional sutures inserted is 1 or more.
7. The method of Claim 6 wherein the number of said additional sutures is determined by the width of the symphysis pubis.
- 15 8. The method of any of Claims 4 to 7 including the step of dividing the fundiform ligament prior to said step of drawing the skin of the junction site of the scrotum.
- 20 9. A method of widening a penis wherein a block of fat and attached dermis (dermal fat graft) is excised from the patient, the penis is degloved, the dermal fat graft is sutured to the exposed Bucks fascia and then reducing the penile skin.

- 30 -

10. A method as claimed in Claim 9 wherein the dermal fat grafts are harvested from either the buttocks, lower back or lower abdomen.
11. A method of lengthening and widening a penis, the
5 lengthening using the method as claimed in Claim 4 and the widening using the method as claimed in Claim 1 wherein the dermal fat graft is sutured to the exposed Bucks fascia prior to the tying of the sutures which maintain the lengthening of the penis.
- 10 12. A method of lengthening the penis of a male substantially as herein described.
13. A method of widening a penis substantially as herein described.
14. A method of lengthening and widening a penis
15 substantially as herein described.
15. A method of enhancement phalloplasty of a human penis in patients who are about to have or already have in place an artificial erection device; said penis having a structure including a first corpus cavernosum, a second
20 corpus cavernosum, a corpus spongiosum, a Buck's fascia and a dorsal neurovascular bundle; said method including the steps of degloving the penis to expose the Buck's fascia; freeing the dorsal neurovascular bundle and separating the corpus spongiosum from the inferior

- 31 -

surface of both said first and said second corpus cavernosum; dividing said first and second corpus cavernosum circumferentially; said method further including the step of following a post-operative treatment regime.

- 5
16. The method as claimed in claim 15 wherein said step of separating the corpus spongiosum from the inferior surface of both said first and said second corpus cavernosum comprises a dissection so as to enable the first and second corpus cavernosum to be elongated
- 10
- without dividing the corpus spongiosum.
17. The method as claimed in claim 15 or claim 16 wherein said artificial erection device comprises a corporal cylinder which is longer than the corporal cylinder presently in place, either where the patient already has
- 15
- an artificial erection device in place or longer than the corporal cylinder which was measured when the corporotomy and dilatation of the corpus was performed earlier in the procedure.
- 20
18. A method as claimed in claim 16 wherein the increase in length of the corporal cylinder is of the order of one or more cm.
19. A method as claimed in any one of claims 15 to 18 wherein a gap formed in the first or second corpus

- 32 -

cavernosum is filled by suturing in place an inverted dermal graft from which the epidermis has been removed.

20. A method as claimed in claim 19 wherein the dermo epidermal surface is the inner most surface applied to the corporal cavity.

21. A method of enhancement phalloplasty as claimed in any one of claims 15 to 20 wherein widening of the penis is also required and wherein widening is effected by using a dermal fat graft.

22. The method of claim 21 wherein the fat graft is sutured to the exposed Bucks fascia and when the graft reaches a defect in the Buck's fascia corresponding to the division of the first or second corpus cavernosum the edges of the graft are sutured to the Buck's fascia circumferentially and to a distal portion of the first or second corpus cavernosum without dividing the graft as a separate phenomenon.

23. A method of enhancement phalloplasty as claimed in claim 22 wherein if the patient has a very thickened wall of the first or second corpus cavernosum, a first dermal fat graft is placed into the defect in the Buck's fascia and then a second dermal fat graft is placed into the defect.

24. A method of enhancement phalloplasty as claimed in claim

- 33 -

23 wherein if the patient has a very thickened wall of the corpus cavernosum, the gap in the wall of the corpus cavernosum is filled by using a gortex graft, a saphenous or other vein patch, temporalis or other fascia such as the fascia lata or dextron mesh or silastic sheeting or other appropriate material and then said second dermal fat graft is applied.

25. A method as claimed in any one of claims 15 to 24 further including an additional step wherein the degloved penis is reduced and the proximal wounds are trimmed and closed in layers.

26. A method of lengthening and widening a penis, the lengthening using the method as claimed in any one of claims 1 to 25 wherein a block of fat and attached dermis (dermal fat graft) is excised from the patient, the penis is degloved, the dermal fat graft is sutured to the exposed Bucks fascia prior to the tying of the sutures which maintain the lengthening of the penis.

27. A method of enhancement phalloplasty substantially as hereinbefore described with reference to the examples of the particular operations given in the specification.

28. A method for penile enlargement further including the step of application of a post-operative treatment regime thereby to maintain outcome of enlargement.

- 34 -

29. A method of penile enlargement further including the step of application of a post-operative treatment regime.
30. The method of claims 28 or 29 wherein penile enlargement
5 comprises one or more of lengthening or widening.
31. The method of any previous claim further including the step of treatment for buried penis condition.
32. The method of any previous claim wherein said post-operative treatment regime comprises application of a
10 drug treatment regime.
33. The method of any previous claim wherein said post-operative treatment regime comprises application of an exercise regime.
34. An exercise regime for application following application
15 of the method of any previous claim.
35. A drug treatment regime for application following application of the method of any one of claims 1 to 33.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/00400

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. 7: A61B 17/00, A61F 2/26

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI, PubMed keywords: phallus, penis, penile, lengthen, widen, enlarge, augmentation, phalloplasty, ligament, corpus, cavernosum, penoplasty, micropenis, treatment, exercise, dressing, bath, sterile, wrap, regime, fundiform and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X, Y | ALTER G. "Girth Enlargement" (online) (retrieved 14 May 2003), earliest known publication date (via <URL:http://www.archive.org>) is 5 May 1998 Retrieved from the Internet <URL:http://www.altermd.com/penhancement/girth.htm> See the whole document. | 1 - 3 |
| Y | | 15 - 25 |
| X | | 28 - 32, 35 |
| X, Y | "Penis Lengthening Surgery - Questions and Answers" (online) (retrieved 14 May 2003), earliest known publication date (via <URL:http://www.archive.org>) is 30 January 1997 Retrieved from the Internet <URL:http://www.psurg.com/PL4QA.htm> See the whole document. | 1 - 3 |
| Y | | 15 - 25 |
| X | | 28 - 32, 35 |

☒ Further documents are listed in the continuation of Box C

☒ See patent family annex

| | |
|---|--|
| * Special categories of cited documents: | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" Document defining the general state of the art which is not considered to be of particular relevance | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" earlier application or patent but published on or after the international filing date | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" Document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" document member of the same patent family |
| "O" Document referring to an oral disclosure, use, exhibition or other means | |
| "P" Document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search
1 July 2003

Date of mailing of the international search report
07 JUL 2003

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/00400

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---------------------|---|-----------------------------|
| X, Y Y X | JAMES D. "The Perfect Penis in about an Hour" (online) (retrieved 14 May 2003), earliest known publication date (via <URL:http://www.archive.org>) is 3 March 2001 Retrieved from the Internet <URL:http://www.psurg.com/humber99.html> See the whole document. | 1 - 3 15 - 25 28 - 35 |
| X, Y Y X L | AU 53864/98 (742359) B (MOORE) 3 January 2002 See the claims The instant application claims an earlier priority from this document. However this citation claims an earlier priority from another application by the same applicant, indicating that the application from which priority is claimed may not be the first application for the invention concerned. It casts doubt that claim 15 in this instance is able to claim a priority from 3 April 2002 in this instance. | 1 - 3 26 9, 10, 13 |
| X | ALTER G.J. "Penile Enlargement Surgery". Techniques in Urology, 1998, Vol 4, No. 2, pp. 70-76 See page 71 col 1; page 72 col 2; page 74 col 1; page 75 col 2 | 1 - 3, 28 - 35 |
| X | ALTER G.J. "Augmentation Phalloplasty". Urologic clinics of North America, 1995, Vol 22, No. 4, pp887- 902 See page 890 col 1; page 895 col 2; page 896 col 1; Fig 9; page 898 col 1; page 901 col 1 | 1 - 3, 28 - 35 |
| X | LUE T.F. and EL-SAKKA A.I. "Lengthening Shortened Penis Caused by Peyronie's Disease Using Circular Venous Grafting and Daily Stretching with a Vacuum Erection Device". Journal of Urology, April 1999, Vol 161, pp 1141 - 1144 See page 1141 col 1; page 1142 col 1; page 1143 col 1; page 1144 col 1. | 15, 16, 17, 25, 28 - 35 |
| X L | AUSTONI E. and GUARNERI A. and CAZZANIGA A. "A New Technique for Augmentation Phalloplasty: Albugineal Surgery with Bilateral Saphenous Graft -Three Years of Experience". European Urology, 2002 Vol 42, pp 245 - 253 See page 249 col 1 Some of the claims do not appear to be entitled to the priority date of the instant application. This citation was published before the filing date. | 28 - 32, 35 |
| X | AUSTONI E. and GUARNERI A. and GATTI G. "Penile elongation and thickening - myth? Is there a cosmetic or medical indication?", Andrologia, 1999, 31 (Suppl. 1) pp 45 - 51 See page 47; page 50 col 1 | 28 - 34 |
| X | SHIRONG L. and XUAN Z. and ZHENGXIANG W. and DONGLI F. and JULONG W. and DONGYUN Y. "Modified Penis Lengthening Surgery: Review of 52 Cases", Plastic and Reconstructive Surgery, February 2000, pp 596 - 599 See page 599 | 29 - 32, 35 |

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/00400

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------------------|--|-----------------------|
| P, X, Y P, Y L | AU 79900/98 (760083) B (MOORE) 8 May 2003 See the claims This citation gains its priority from 13 August 1997. It is an earlier patent by the same applicant, indicating that the application from which priority is claimed may not be the first application for the invention concerned. It casts doubt that claim 15 in this instance is able to claim a priority from 3 April 2002 in the instant application. | 15 - 25, 27 26 |
| Y | RIGAUD G. and BERGER R.E.. "Corrective Procedures for Penile Shortening due to Peyronies's Disease", The Journal of Urology, February 1995, Vol 153, pp368 - 370 See page 369 col 1 | 15 - 18 |

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/00400

Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos :
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos :
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See the Supplemental Sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/00400

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 3, 9, 10, 13 at least are directed to a method of widening a penis. It is considered that the use of a dermal graft sutured to the exposed Bucks fascia and then reducing the penile skin comprises a first "special technical feature".
2. Claims 4 to 8, 12 at least are directed to a method of lengthening the penis. It is considered that dividing the suspensory ligament against the body of the symphysis pubis down to the inferior pubic arch and along the inferior surface of both the right and left conjoined inferior pubic rami comprises a second "special technical feature".
3. Claims 15 to 20, 27 at least are directed to a method of enhancement phalloplasty. It is considered that freeing the dorsal neurovascular bundle and separating the corpus spongiosum from the inferior surface of both said first and said second corpus cavernosum comprises a third "special technical feature."
4. Claims 28 to 33 are directed to a method of penile enlargement. It is considered that the post operative treatment regime following penile enlargement, whether exercise, drug or other, comprises a fourth "special technical feature".

The feature common to all of the claims is the use of a post operative treatment regime. However this common feature is generic in the art: see for example a partially completed search has found the following Internet documents;

<http://www.altermd.com/penhancement/girth.htm> published 5 May 1998

<http://www.psurg.com/PL4QA.htm> published 30 January 1997

<http://www.psurg.com/humber99.html> published 3 March 2001

Consequently the common feature does not constitute "a special technical feature" within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art. Since there exists no other common feature which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence, no technical relationship within the meaning of PCT Rule 13 between the different inventions can be seen. Consequently it appears that a posteriori, the claims do not satisfy the requirement of unity of invention.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU03/00400

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | Patent Family Member |
|---|----------|----------------------|
| AU | 79900/98 | NONE |
| AU | 54864/98 | NONE |
| | | END OF ANNEX |